U.S. Application No.: 10/537,462

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the

application:

LISTING OF CLAIMS:

1. (currently amended): A fat emulsion with which a local anaesthetic is mixed

before use, and which comprises propofol, an oily component, and an emulsifier, the fat

emulsion further comprising a stabilizer selected from the following (a), (b), (c), or (d):

(a) at least one phospholipid selected from the group consisting of phosphatidylglycerol,

phosphatidic acid, phosphatidylinositol, and phosphatidylserine wherein a fatty acid esterified to

a glycerol moiety is a C₁₈₋₂₂ linear or branched, saturated or unsaturated fatty acid;

(b) at least one phospholipid derivative selected from phosphatidylethanolamines

modified with polyalkyleneglycol, wherein a fatty acid esterified to a glycerol moiety is a C₁₀₋₂₂

linear or branched, saturated or unsaturated fatty acid;

(c) at least one fatty acid selected from the group consisting of C_{10-22} linear or branched,

saturated or unsaturated fatty acids; or

(d) a mixture of at least two members selected from the above groups (a), (b), and (\underline{Cc}) ,

wherein

the stabilizer (a), (b), or (c) is present at a concentration of 0.01 to 1 w/v%, 0.01 to 1

w/v%, 0.05 to 5 w/v%, respectively, per the total amount of the fat emulsion and the local

anaesthetic to be mixed therewith before use.

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2. (currently amended): The fat emulsion according to Claim 1, wherein

(1) propofol is present at a concentration of 0.4 to 5 w/v%,

(2) an-the oily component is present at a concentration of 2 to 20 w/v%, and

(3) an-the emulsifier is present at a concentration of 0.4 to 5 w/v%, per the total amount

of the fat emulsion and the local anaesthetic to be mixed therewith before use.

3. (currently amended): The fat emulsion according to Claim 1, wherein a-the local

anaesthetic is at least one member selected from the group consisting of lidocaine, mepivacaine,

bupivacaine, ropivacaine, dibucaine, procaine, procaine chloride, tetracaine and

pharmacologically acceptable acid addition salts thereof.

4. (currently amended): The fat emulsion according to Claim 1, wherein the local

anaesthetic is present at a concentration of 0.01 to 1 w/v%, per the total amount of the fat

emulsion and the local anaesthetic to be mixed therewith before use.

5. (currently amended): The fat emulsion according to Claim 1, wherein the

stabilizer is at least one phospholipid (a) selected from the group consisting of

phosphatidylglycerol, phosphatidic acid, phosphatidylinositol, and phosphatidylserine, wherein a

fatty acid esterified to a glycerol moiety is a C₁₈₋₂₂ linear or branched, saturated or unsaturated

fatty acid.

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6. (canceled).

7. (previously presented): The fat emulsion according to Claim 1, wherein the stabilizer is at least one phospholipid (a) selected from the group consisting of distearoylphosphatidylglycerol, dioleoylphosphatidylglycerol, distearoylphosphatidic acid, distearoylphosphatidylinositol, dioleoylphosphatidylinositol, distearoylphosphatidylserine, and dioleoyl-phosphatidylserine.

- 8. (currently amended): The fat emulsion according to Claim 5, wherein the stabilizer is present at a concentration of 0.03 to 1 w/v%, per the total amount of the fat emulsion and the local anaesthetic to be mixed therewith before use.
- 9. (original): The fat emulsion according to Claim 1, wherein the stabilizer is at least one phospholipid derivative (b) selected from phosphatidylethanolamines modified with polyalkyleneglycol, wherein a fatty acid esterified to a glycerol moiety is a C₁₀₋₂₂ linear or branched, saturated or unsaturated fatty acid.
 - 10. (canceled).

11. (original): The fat emulsion according to Claim 1, wherein the stabilizer is at least one phospholipid derivative (b) selected from the group consisting of

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distearoylphosphatidylethanolamine-polyethylene glycol 5000, distearoylphosphatidylethanolamine-polyethylene glycol 3000, and distearoylphosphatidylethanolamine-polyethylene glycol 2000.

- 12. (currently amended): The fat emulsion according to Claim 9, wherein the stabilizer is present at a concentration of 0.1 to 1 w/v%, per the total amount of the fat emulsion and the local anaesthetic to be mixed therewith before use.
- 13. (original): The fat emulsion according to Claim 1, wherein the stabilizer is at least one fatty acid (c) selected from the group consisting of C_{10-22} linear or branched, saturated or unsaturated fatty acids.
 - 14. (canceled).
- 15. (original): The fat emulsion according to Claim 1, wherein the stabilizer is at least one fatty acid (c) selected from the group consisting of decanoic acid, lauric acid, myristic acid, palmitic acid, stearic acid, arachidic acid, isomyristic acid, isopalmitic acid, and oleic acid.
- 16. (currently amended): The fat emulsion according to Claim 13, wherein the stabilizer is present at a concentration of 0.1 to 5 w/v%, per the total amount of the fat emulsion and the local anaesthetic to be mixed therewith before use.

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17. (currently amended): A fat emulsion containing container having a multi-compartment that is divided with a partition in such a manner as to allow <u>contents in</u> the compartments to <u>communicate come into contact</u> with one another <u>by opening the partition</u>, which container <u>comprises comprising</u> one compartment containing the fat emulsion according to Claim 1 and another compartment containing a local anaesthetic.

- 18. (currently amended): A pain-relieving fat emulsion comprising propofol, an oily component, an emulsifier, a stabilizer, and a local anaesthetic, wherein the stabilizer is selected from the following (a), (b), (c), or (d):
- (a) at least one phospholipid selected from the group consisting of phosphatidylglycerol, phosphatidic acid, phosphatidylinositol, and phosphatidylserine wherein a fatty acid esterified to a glycerol moiety is a C_{18-22} linear or branched, saturated or unsaturated fatty acid;
- (b) at least one phospholipid derivative selected from phosphatidylethanolamines modified with polyalkyleneglycol, wherein a fatty acid esterified to a glycerol moiety is a C_{10-22} linear or branched, saturated or unsaturated fatty acid;
- (c) at least one fatty acid selected from the group consisting of C_{10-22} linear or branched, saturated or unsaturated fatty acids; or
- (d) a mixture of at least two members selected from the above groups (a), (b), and (Cc), wherein

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the stabilizer (a), (b), or (c) is present at a concentration of 0.01 to 1 w/v%, 0.01 to 1 w/v%, and 0.05 to 5 w/v%, respectively, in the fat emulsion.

19. (currently amended): The pain-relieving fat emulsion according to Claim 18, wherein

- (1) propofol is present at a concentration of 0.4 to 5 w/v%,
- (2) an the oily component is present at a concentration of 2 to 20 w/v%,
- (3) an-the emulsifier is present at a concentration of 0.4 to 5 w/v%, and
- (4) a-the local anaesthetic is present at a concentration of 0.01 to 1 w/v%, in the fat emulsion.
- 20. (currently amended): The pain-relieving fat emulsion according to Claim 18, wherein a-the local anaesthetic is at least one member selected from the group consisting of lidocaine, mepivacaine, bupivacaine, ropivacaine, dibucaine, procaine, procaine chloride, tetracaine and pharmacologically acceptable acid addition salts thereof.
- 21. (currently amended): The pain-relieving fat emulsion according to Claim 18, wherein the stabilizer is at least one phospholipid (a) selected from the group consisting of phosphatidylglycerol, phosphatidic acid, phosphatidylinositol, and phosphatidylserine, wherein a fatty acid esterified to a glycerol moiety is a C₁₈₋₂₂ linear or branched, saturated or unsaturated fatty acid.

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22. (canceled).

23. (previously presented): The pain-relieving fat emulsion according to Claim 18,

wherein the stabilizer is at least one phospholipid (a) selected from the group consisting of

distearoylphosphatidylglycerol, dioleoylphosphatidylglycerol, distearoylphosphatidic acid,

dioleoylphosphatidic acid, distearoylphosphatidylinositol, dioleoylphosphatidylinositol,

distearoylphosphatidylserine, and dioleoylphosphatidylserine.

24. (original): The pain-relieving fat emulsion according to Claim 21, wherein the

stabilizer is present at a concentration of 0.03 to 1 w/v% in the fat emulsion.

25. (original): The pain-relieving fat emulsion according to Claim 18, wherein the

stabilizer is at least one phospholipid derivative (b) selected from phosphatidylethanolamines

modified with polyalkyleneglycol, wherein a fatty acid esterified to a glycerol moiety is a C₁₀₋₂₂

linear or branched, saturated or unsaturated fatty acid.

26. (canceled).

27. (original): The pain-relieving fat emulsion according to Claim 18, wherein the

stabilizer is at least one phospholipid derivative (b) selected from the group consisting of

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distearoylphosphatidylethanolamine-polyethylene glycol 5000, distearoylphosphatidylethanolamine-polyethylene glycol 3000, and

distearoylphosphatidylethanolamine-polyethylene glycol 2000.

28. (original): The pain-relieving fat emulsion according to Claim 25, wherein the

stabilizer is present at a concentration of 0.1 to 1 w/v% in the fat emulsion.

29. (original): The pain-relieving fat emulsion according to Claim 18, wherein the

stabilizer is at least one fatty acid (c) selected from the group consisting of C₁₀₋₂₂ linear or

branched, saturated or unsaturated fatty acids.

30. (canceled).

31. (original): The pain-relieving fat emulsion according to Claim 18, wherein the

stabilizer is at least one fatty acid (c) selected from the group consisting of oleic acid, isomyristic

acid, isopalmitic acid, decanoic acid, lauric acid, myristic acid, palmitic acid, stearic acid, and

arachidic acid.

32. (original): The pain-relieving fat emulsion according to Claim 29, wherein the

stabilizer is present at a concentration of 0.05 to 0.2 w/v% in the fat emulsion.

Attorney Docket No.: Q88123

AMENDMENT UNDER 37 C.F.R. § 1.111 U.S. Application No.: 10/537,462

33. (previously presented): A method for manufacturing a pain-relieving fat emulsion, the method comprising:

mixing a local anaesthetic with a fat emulsion comprising propofol, an oily component, an emulsifier, and a stabilizer, wherein the stabilizer is selected from the following (a), (b), (c), or (d):

- (a) at least one phospholipid selected from the group consisting of phosphatidylglycerol, phosphatidic acid, phosphatidylinositol, and phosphatidylserine wherein a fatty acid esterified to a glycerol moiety is a C_{18-22} linear or branched, saturated or unsaturated fatty acid;
- (b) at least one phospholipid derivative selected from phosphatidylethanolamines modified with polyalkyleneglycol, wherein a fatty acid esterified to a glycerol moiety is a C_{10-22} linear or branched, saturated or unsaturated fatty acid;
- (c) at least one fatty acid selected from the group consisting of C_{10-22} linear or branched, saturated or unsaturated fatty acids; or
- (d) a mixture of at least two members selected from the above groups (a), (b), and (c), to thereby obtain a fat emulsion, wherein

the stabilizer (a), (b), or (c) is present at a concentration of 0.01 to 1 w/v%, 0.01 to 1 w/v%, and 0.05 to 5 w/v%, respectively, in the fat emulsion.

34. (canceled).